UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,879	07/28/2003	Michael M. Sekar	ABIOS.001A	3875

20995 7590 12/29/2005

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/628,879	SEKAR ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/17/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claim 1 is acknowledged and has been entered.

2. Claims 1-21 are currently pending

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, it is unclear how the analyte is detected. Currently it is assumed that the aptamer bound to the solid support is specific for the analyte, and that the measurement made is indicative of the analyte bound, but further clarification would be appreciated.

5. The remaining claims are indefinite due to their dependence on an indefinite claim.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 9, 11, 12, 14, 15, 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al [US 6,544,776] in view of Tomei et al [US 5,037,207].

With respect to claim 1, Gold et al teach aptamers immobilized to the surface of biochips (column 10, lines 60-67), and measurement of fluorescence anisotropy to determine presence of target molecules (column 16, lines 15-36). Gold et al fail to specify how the aptamers are illuminated.

Tomei et al, however, teach a means of direct polarized illumination (fig. 4) for fluorescence anisotropy (column 7, lines 55-65). Tomei et al further teach that this means eliminates the need for mechanical translation stages for targets, and is capable of scanning targets of any size without gross stage movement (column 2, lines 21-30).

Therefore, it would have been obvious in the method of Gold et al to illuminate the aptamers with the illumination means of Tomei, in order to eliminate the need for mechanical translation stages for targets, and providing a illumination means capable of scanning targets of any size without gross stage movement.

1. With respect to claim 9, Gold et al teach the use of fluorescein (column 12, lines 16-20).

2. With respect to claims 11-12, Gold et al teach a 4x4 array of aptamers (fig. 1, column 3, lines 28-38).

3. With respect to claims 14, 15, Gold et al teach an array of photoreactive aptamers, where irradiation will covalently attach only the correct protein to the correct photoactivitable aptamer present at a defined area of a matrix laid out on the surface of the chip (column 18, lines 14-20), where multiple different probes may be used (column 14, lines 35-45).

4. With respect to claims 17, 18, 21, Gold et al teach that the attached nucleic acid ligands will bind to components of the blood plasma or other bodily fluid of an individual known to be

suffering from a particular disease where the target molecules are not found in the bodily fluid of healthy individuals (col. 2, line 65 – col. 3, line 11).

5. With respect to claims 19-20, Gold et al teach that the target molecule can be a protein or metabolite (column 4, lines 45-58).

8. Claims 1, 8, 9, 11-13, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Potyrailo et al [Potyrailo et al, Adapting selected nucleic acid ligands to biosensors, 1998, Anal Chem 70:3419-3425] in view of Tomei et al [US 5,037,207].

With respect to claims 1, 11, Potyrailo et al teach aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1) and the use of fluorescence anisotropy to detect the bound labeled aptamer probe-analyte binding event using a vertically polarized laser (p.3420, col.2). Potyrailo et al fail to teach the direct illumination of the aptamers with polarized light.

Tomei et al, however, teach a means of direct polarized illumination (fig. 4) for fluorescence anisotropy (column 7, lines 55-65). Tomei et al further teach that this means eliminates the need for mechanical translation stages for targets, and is capable of scanning targets of any size without gross stage movement (column 2, lines 21-30).

Therefore, it would have been obvious in the method of Potyrailo et al to illuminate the aptamers with the illumination means of Tomei, in order to eliminate the need for mechanical translation stages for targets, and providing a illumination means capable of scanning targets of any size without gross stage movement.

It should be noted that although Potyrailo et al specifies that evanescent wave is more advantageous than direct sample illumination, Potyrailo et al do not preclude the use of direct sample illumination (p.3422, col.2, lines 37-43).

6. With respect to claim 8, the aptamers comprise 15-mer single-stranded DNA that bind to the blood-clotting factor thrombin (p.3421, col.2).

7. With respect to claim 9, Potyrailo et al teach the use of fluorescein isothiocyanate (p. 3419, col.2).

8. With respect to claims 12, 13, since Potyrailo et al teach multiple anti-thrombin DNA aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1), each aptamer could be considered a single addressable location (fig.1).

9. With respect to claim 16, a vertically polarized laser is used to detect fluorescence anisotropy (p.3420, col.2).

9. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gold et al [US 6,544,776] in view of Tomei et al [US 5,037,207] and further in view of Wei et al [US 6,576,419].

With respect to claim 10, Gold et al teach aptamers immobilized to the surface of biochips (column 10, lines 60-67), and measurement of fluorescence anisotropy to determine presence of target molecules (column 16, lines 15-36), as discussed above. Gold et al and Tomei et al fail to teach the use of carboxyfluorescein instead of fluorescein (column 12, lines 16-20) to label the aptamer.

Wei et al, however, teach the use of fluorescein and carboxy fluorescein (column 15, example VI), showing that they are equivalent structures known in the art.

Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute

carboxyfluorescein for fluorescein in the method of Gold et al and Tomei et al, as suggested by Wei et al.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Potyrailo et al [Potyrailo et al, Adapting selected nucleic acid ligands to biosensors, 1998, Anal Chem 70:3419-3425] in view of Tomei et al [US 5,037,207] and further in view of Wei et al [US 6,576,419].

With respect to claim 10, Potyrailo et al teach anti-thrombin DNA aptamers (p.3419, col.1) immobilized to a glass surface (p.3420, col.1) and the use of fluorescence anisotropy to detect the bound labeled aptamer probe-analyte binding event using a vertically polarized laser (p.3420, col.2). Potyrailo et al and Tomei et al fail to teach the use of carboxyfluorescein instead of fluorescein (column 12, lines 16-20) to label the aptamer.

Wei et al, however, teach the use of fluorescein and carboxy fluorescein (column 15, example VI), showing that they are equivalent structures known in the art.

Therefore, because these two were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute carboxyfluorescein for fluorescein in the method of Potyrailo et al and Tomei et al, as suggested by Wei et al.

Response to Arguments

11. Applicant's arguments, see p. 5-8, filed October 17, 2005, with respect to the rejections under 35 U.S.C. 103(a) have been fully considered and are persuasive. The rejection of claims 1-21 under 35 U.S.C. 103(a) has been withdrawn.

Allowable Subject Matter

12. Claims 2-7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

13. No claims allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Exainer
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
12/27/05